REMARKS

Claim Amendments

Claims 3-21 are pending. Claims 1 and 8-13 stand withdrawn. Claims 3-7 have been amended. Claims 1 and 2 have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue cancelled subject matter in continuation or divisional patent applications. New claims 14-21 are presented for examination. Support for these new claims and amendments can be found throughout the specification and the claims as originally filed, for example, at page 9, lines 9-14; page 10, lines 12-18, 23-30; page 11, lines 14-18; page 12, lines 6-32; page 13, lines 5-21. Applicants respectfully requests entry of the above amendments to the claims and submit that the above amendments do not constitute new matter. Applicants further submit that newly presented claims 14-21 are within elected Group II.

Claim Objections

Claims 3 and 4 were objected to due to informalities. Applicants have amended claims 3 and 4 rendering this objection *moot*.

Claim Rejection – 35 U.S.C. § 112, second paragraph

Claims 2-7 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully disagree and traverse this rejection.

Claim 2 was rejected because the claim element "a DNA that hybridizes under stringent conditions with the nucleotide sequences of SEQ ID NO: 1" was allegedly indefinite. Applicants have accepted the Examiner's suggestion, canceling claim 2 and amending claims 3 and 5 to recite "a DNA that hybridizes with the nucleotide sequence of SEQ ID NO: 1 under stringent conditions of 6X SSC and 40% formamide at 25°C for hybridization, and 1X SSC at 55°C washing" to clarify the term stringent conditions.

Claim 4 was rejected because allegedly it was "not clear if the enhancer element has to be operably linked or attached to the report gene". Applicants have amended claim 4 to restate the phrase "equipped with" as "comprising a reporter gene operably linked to an enhancer element

consisting of the nucleotide sequence of SEQ ID NO: 4 or SEQ ID NO: 5" rendering this rejection *moot*.

Claim 4 was rejected because allegedly "there are no upper limits to additions, substitutions, deletions or insertions envisioned by the claim." Applicants submit that they are currently pursuing subject matter where the claim recites "consisting of the nucleotide sequence of SEQ ID NO: 4 or SEQ ID NO: 5" rendering this rejection *moot*.

Claim 5 was rejected because there allegedly was "no relationship stated between the subject matter of the independent claim 4 and the KLF-9-encoding DNA." Applicants have amended claim 5 to recite an isolated cell comprising a DNA molecule comprising the nucleotide sequence of SEQ ID NO: 1 or a DNA molecule that hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO: 1. As is taught in the specification, the nucleotide sequence of SEQ ID NO: 1 encodes a KLF9 protein, rendering this rejection *moot*. *See* Specification at page 10, lines 6-13.

Claims 4 and 5 were rejected because they were allegedly incomplete. Applicants have amended both claims 4 and 5 to be drawn to isolated cells comprising a reporter gene operably linked to an enhancer element in claim 4 and a KLF9 encoding DNA molecule in claim 5. Applicants submit that as presented, both claims 4 and 5 are complete, rendering this rejection *moot*.

Claim Rejection – 35 U.S.C. § 112, first paragraph (enablement)

Claim 3 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully disagree and traverse this rejection.

As a preliminary matter, Applicants note that they have amended claim 3 to recite "a pharmaceutical composition comprising: (1) a DNA molecule comprising the nucleotide sequence of SEQ ID NO:1; or (2) a DNA molecule that hybridizes with the nucleotide sequence of SEQ ID NO:1 under stringent conditions of 6X SSC and 40% formamide at 25°C for hybridization, and 1X SSC at 55°C for washing." To the extent that the rejection applies to the claim as amended, Applicants make the following remarks.

The Office Action bases the enablement rejection on the supposition that the art of gene therapy is "unpredictable" and the "specification has not taught appropriate vectors, means or modes of administration for use..." citing Post, *et al.* (2001) *See* Office Action at page 6.

Applicants respectfully submit that claim 3 as instantly presented is drawn to a pharmaceutical composition and not a gene therapy method. Further, the specification teaches how to make and use the claimed pharmaceutical composition comprising a DNA molecule comprising the nucleotide sequence of SEQ ID NO: 1 or DNA molecule that hybridizes to said sequence under stringent conditions. Specification at page 10, lines 6-18.
In contrast with gene therapy methods, the instant pharmaceutical composition comprises a stimulatory agent and does not work to replace a defective gene.

Applicants submit that the uses (*e.g.*, utility) of the claimed pharmaceutical composition is not necessarily limited to therapeutic methods. For instance, the specification teaches that the composition may be used to make a cell for use in screening assays. Specification at page 4, line 35 to page 5, line 6. Additionally, the specification teaches that the composition may be used in a screening assay to identify an adiponectin expression-inducing substance and screening for a therapeutic agent for treating an obesity or an obesity-related disease. Specification at page 5, lines 7-30, page 16, lines 18-36. Also the claimed pharmaceutical composition may be used in animal models to study obesity and screen for therapeutic agents to treat obesity. Specification at page 17, lines 16-24.

In sum, a person of skill in the art has sufficient guidance from the specification in the form of the examples, detailed activities, and methods for testing for them, that a person of skill in the art could make and use pharmaceutical composition comprising: (1) a DNA molecule comprising the nucleotide sequence of SEQ ID NO:1; or (2) a DNA molecule that hybridizes with the nucleotide sequence of SEQ ID NO:1 under stringent conditions.

Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim Rejection – 35 U.S.C. § 112, first paragraph (written description)

Claims 2-7 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully disagree and traverse this rejection.

As a preliminary matter, Applicants have cancelled claim 2 and amended claims 3, 4, and 5 to recite DNA molecules comprising the nucleotide sequence of SEQ ID NO: 1 operably linked to an enhancer element including the nucleotide sequence of SEQ ID NO: 4 or 5. To the extent that the rejection applies to the claim as amended, Applicants make the following remarks.

The Office Action alleged that the Kruppel-like factor 9 (a transcription factor) and regulatory sequence lacked a clear description of the characteristics of DNA absent a definition of "stringent conditions." Office Action at page 8. Applicants have accepted the Examiner's suggestion, canceling claim 2 and amending claims 3 and 5 to recite "a DNA that hybridizes with the nucleotide sequence of SEQ ID NO: 1 under stringent conditions of 6X SSC and 40% formamide at 25°C for hybridization, and 1X SSC at 55°C washing" to clarify the term stringent conditions. Specification at page 10, lines 14-19.

The Office Action further alleges that claim 4 "did not require that the nucleic acid [have] any particular conserved structure" and the "only functional feature [is] that it has an undisclosed enhancer element." Office Action at page 9. Applicants have amended claim 5 as discussed above. Applicants further submit the enhancer element (*e.g., cis* factor) is a KLF9 binding element that promotes the KLF9 mediated adiponectin gene expression. For example, the enhancer element may be the nucleotide sequence of SEQ ID NO: 5 that corresponds to a regulatory element located at positions –188 to –157 upstream of the adiponectin gene. Specification at page 13, lines 10-15. Further, the specification teaches that substitution of amino acids with similar properties into the recited sequence is reasonably expected to maintain protein activity. Specification at page 9, line 28 to page 10, line 4. Further, the specification provides examples of methods for obtaining proteins that are functionally equivalent to KLF9 including methods that modify the DNA of SEQ ID NO: 1 and then synthesize proteins based on the modified DNAs. Specification at page 10, line 23-30. In addition, the Office Action states that the sequence of SEQ ID NO: 5 "meets the written description provision of 35 U.S.C. § 112,

first paragraph." Office Action at page 11. Applicants submit that the specification has clearly described the enhancer element of claim 4.

Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim Rejection — 35 U.S.C. § 102(b)

Claim 2 was rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Hayashizaki Y, data base entry "db_xref="FANTOM_DB:4632425M20". Applicants respectfully traverse this rejection.

Applicants have cancelled claim 2 rendering this rejection *moot* and submit that this reference does not anticipate claim 3 as instantly presented.

Claims 4, 6, and 7 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 6,582,909 ("the '909 patent"). Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants have amended claims 4, 6, and 7 rendering this rejection *moot*. To the extent that the rejection applies to the claim as amended, Applicants make the following remarks.

The Office Action asserts that the '909 patent discloses a nucleotide sequence of the 5' regulatory region of the adipocyte specific APM1 gene (nucleotides 4623-4654)...[where a] regulatory sequence contains the promoter and the enhancer of a particular gene and is situated in the untranslated region of the gene." Office Action at page 13. In contrast, the '909 patent discusses a reporter gene in passing without reference to the inclusion of an enhancer element. Therefore, Applicants submit that the '909 patent does not teach or suggest a reporter gene operably linked to an enhancer element *consisting of* the nucleotide sequence of SEQ ID NO: 4 or SEQ ID NO: 5.

Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Applicants believe that no fees are required for entry of this Response. However, in the event that any fees are deemed necessary by the U.S. Patent and Trademark Office to enter and consider this Response or to maintain the present application pending, please charge the fees to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

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